IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Vega *et al.*Serial No.: 10/022,249

Confirmation No.: 7196

Filed:

December 17, 2001

For:

HIGH THROUGHPUT

DIRECTEDEVOLUTION BY RATIONAL MUTAGENESIS

Art Unit:

1643

Examiner:

Unassigned

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TRANSMITTAL LETTER

Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Transmitted herewith are an Information Disclosure Statement, Forms PTO-1449 (8 pages) and cited references for filing in connection with the above-identified application.

(X) The Commissioner is hereby authorized to charge any fees that may be due under 37 C.F.R. §§1.16-1.17 in connection with this paper or with this application during its entire pendency to Deposit Account No. 50- 1213. A duplicate of this sheet is enclosed.

Respectfully submitted,

HELLER EHRMAN WHITE & McAULIFFE LLP

By:

Stephanie L. Seidman Registration No. 33,779

Date: November 12, 2002

Attorney Docket No. 37851-911 Address all correspondence to:

Stephanie L. Seidman, Esq.

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INFORMATION DISCLOSURE STATEMENT IN **ACCORDANCE WITH 37 C.F.R. §§ 1.97-1.98**

Commissioner for Patents U.S. Patent and Trademark Office P.O. Box 2327 Arlington, VA 22202

Dear Sir:

Since this Information Disclosure Statement is filed before the receipt of a first Office Action on the merits for the above-captioned application, no filing fee is due. If it is determined that a fee is due, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-1213.

In accordance with the duty of disclosure imposed by 37 C.F.R. §1.56 to inform the Patent Office of all references known by Applicant or Applicant's representative that may be material to the examination of the subject application, Applicant's representative hereby provides this Information Disclosure Statement that is prepared in accordance with 37 C.F.R. §§1.97-1.98. Forms PTO-1449 (8 pages) and copies of the cited documents are provided herewith.

The cited documents, listed on Forms PTO-1449 and supplied herewith, are in the English language with the exception of items Z, AA and AC. Item Z (WO 01/44809) and item AC (FR 2808645), which are in the French language, are provided with an English language translation and Derwent English language abstact (Item AX) describing the subject matter. Item AA (WO 01/86291), which is in the French language, is provided with a Derwent English language abstact (Item AY) describing the subject matter. Certified English language translations of Items Z and AA will be provided at a later date under separate cover. Hence, in accordance with the requirements of 37 C.F.R. § 1.98, as amended effective March 16, 1992, no further explanation of the listed items is necessary.

Applicant also makes known to the Examiner the following related, co-pending U.S. applications and their status:

U.S.S.N. 10/022,249 Vega *et al.* Information Disclosure Statement

U.S.S.N.	Filing Date	Docket No.
10/022,390	12/17/01	912
10/168,075	12/13/00	NA
60/360,085	02/25/02	P918
60/409,898	09/09/02	P922
60/410,258	09/09/02	P923
Foreign App. No.	Filing Date	
EP 00985423.3	12/13/00	
PCT/IB02/03921	08/16/02	
Unassigned	08/16/02	

Although these documents are made known to the Patent and Trademark Office in compliance with Applicant's duty of disclosure, such disclosure is not to be construed as an admission by Applicant or Applicant's representative that any of the references, singly or in any combination thereof, is effective as prior art against the subject application. In accordance with 37 C.F.R. §1.97(h), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made or that no other material information as defined in 37 C.F.R. §1.56(b) exists.

Applicant respectfully requests that the Examiner review the foregoing references and information and that they be made of record in the file history of the above-captioned application.

Respectfully submitted,

HELLER EHRMAN WHITE & McAULIFFE LLP

By:

Stephanie Seidman Registration No. 33,779

Dated: November 12, 2002 Attorney Docket No.: 37851-911 Address all correspondence to: Stephanie Seidman, Esq.

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ATTY. DOCKET NO. 37851-0911

10/022,249

SERIAL NO.

LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE **STATEMENT**

APPLICANT VEGA et al.

FILING DATE December 17, 2001

GROUP 1643

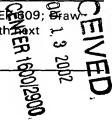
U.S. PATENT DOCUMENTS

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EXAMINER INITIAL		DOCUMENT NUMBER				MBER DATE NAME CLA					SUB CLASS	FILING DATE	
	Α	4	7	9	7	3	6 1	8	01/10/89	Carter et al.	435	320	03/15/85
	В	5	1	3	9	9	4	1	08/18/92	Muzyczka e <i>t al</i> .	435	172.3	10/25/91
	С	5	5	7	1	6	9	8	11/05/96	Ladner <i>et al.</i>	435	69.7	06/18/93
	D	5	7	2	3	3	2	3	03/03/98	Kauffman e <i>t al.</i>	435	172.3	12/02/94
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	F	5	7	6	3	2	3	9	06/09/98	Short et al.	435	172.1	06/18/96
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	Т	6	1	6	5	7	9	3	12/26/00	Stemmer	435	440	05/08/98
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE **STATEMENT**

ATTY.	DOCKET	NO.
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SERIAL NO. 10/022,249

APPLICANT VEGA et al.

FILING DATE December 17, 2001 **GROUP** 1643

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	_		DOCUMENT NUMBER			DATE	NAME	CLASS	SUB CLASS	FILING DATE			
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X* = An English Language Derwent Abstract is Provided.

OTHER ART (Including Author, Title, Date, Pertinent Pages, Etc.)

AD	Ashktorab <i>et al.</i> , "Identification of Nuclear Proteins That Specifically Interact with Adeno-Associated Virus Type 2 Inverted Terminal Repeat Hairpin DNA", <i>Journal of Virology</i> , 63:3034-3039 (1989)
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АН	ATCC accession no. VR-681, "Adeno-associated virus 3 deposited as Adeno-associated virus type 3", (accessed on 09/05/2002)
AI	ATCC accession no. VR-645, "Adeno-associated virus 1 deposited as Adeno-associated (satellite) virus type 1", (accessed on 09/05/2002)
AJ	Atkinson et al., "A high-throughput hybridization method for titer determination of viruses and gene therapy vectors", <i>Nucleic Acids Research.</i> , 26:2821-2823 (1998)
 AK	Altschul et al., "Basic Local Alignment Search Tool", J. Molec. Biol., 215:403-410 (1990)

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO. SERIAL NO. 37851-0911 10/022,249				
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE	APPLICANT VEGA et al.				
STATEMENT	FILING DATE December 17, 2001	GROUP 1643			

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АО	Carillo et al., "The Multiple Sequence Alignment Problem in Biology", SIAM J. Applied Math, 48:1073-1082 (1988)
АР	Cassinotti <i>et al.</i> , "Organization of the Adeno-Associated Virus (AAV) Capsid Gene: Mapping of a Minor Spliced mRNA Coding for Virus Capsid Protein 1", <i>Virology</i> , 167:176-184 (1988)
AQ	Chadeuf <i>et al.</i> , "Efficient recombinant adeno-associated virus production by a stable repcap HeLa cell line correlates with adenovirus-induced amplification of the integrated repcap genome", <i>J. Gene Med.</i> , <u>2</u> :260-268 (2000)
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АТ	Cullen et al., "Analysis of the Physical State of Different Human Papillomavirus DNAs in Intraepithelial and Invasive Cervical Neoplasm", Journal of Virology, 65:606-612 (1991)
AU	Davis <i>et al.</i> , "Mutational Analysis of Adeno-Associated Virus Type 2 Rep68 Protein Endonuclease Activity on Partially Single-Stranded Substrates", <i>Journal of Virology</i> , 74:2936-2942 (2000)
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STATEMENT	FILING DATE December 17, 2001	GROUP 1643			

0	THER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
АХ	Derwent # 013914049, WPI Acc. No. 2001-398262/200142, for French Patent FR 2802645 and PCT Patent Application WO 2001/44809 "Evaluating the performance of complex biological agents in target cells, for selecting gene therapy vectors with optimal properties, comprises constructing a theoretical curve"
AY	Derwent # 014262217, WPI Acc. No. 2002-082915/200211, for PCT Patent Application WO 2001/86291 A1, "Determining titer of biological agent, useful e.g. for gene therapy vectors or vaccines, is based on measuring reaction with cells at constant concentration, over a specified time period"
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BF	Genbank accession no. NC_001829, Nucleotide, "Adeno-associated virus 4, complete genome", (accessed on 09/05/2002)
BG	Genbank accession no. NC_001863, Nucleotide, "Adeno-associated virus 3B, complete genome", (accessed on 09/05/2002)
вн	Genbank accession no. NC_001401, Nucleotide, "Adeno-associated virus 2, complete genome", (accessed on 09/05/02)
ВІ	Genbank accession no. NC_001729, Nucleotide, "Adeno-associated virus 3, complete genome", (accessed on 09/05/02)
ВЈ	Gibbs et al., "Rational Scanning Mutagenesis of a Protein Kinase Identifies Functional Regions Involved in Catalysis and Substrate Interactions", Journal of Biology Chemistry,

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Title: HIGH THROUGHPUT DIRECTED EVOLUTION BY RATIONAL MUTAGENESIS

266:8923-8931 (1991)

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O.	THER AR	RT (Inc	luding	Autho	or, litle	e, Date	e, Pertir	nent <u>F</u>	ages,	Etc.)
зк	Gribskov	et al.,	"Sigma	factors	from <i>E.</i>	coli, B.	subtilis,	phage	SP01,	and ph

	ВК	Gribskov et al., "Sigma factors from E. coli, B. subtilis, phage SP01, and phage T4 are homologous proteins", Nucleic Acids Research, 14:6745-6763 (1986)
	BL	Hermonat, P.L., "Down-regulation of the human c-fos and c-myc proto-oncogene promoters by adeno-associated virus Rep78", Cancer Letters, 81:129-136 (1994)
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	BR	Im <i>et al.</i> , "The AAV Origin Binding Protein Rep68 Is an ATP-Dependent Site-Specific Endonuclease with DNA Helicase Activity", <i>Cell</i> , <u>61</u> :447-457 (1990)
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	BU	Kyostio et al., "Identification of Mutant Adeno-Associated Virus Rep Proteins Which Are Dominant-Negative For DNA Helicase Activity", Biochemical and Biophysical Research Communications, 220:294-299 (1996)
	BV	Kyostio <i>et al.</i> , "Analysis of Adeno-Associated Virus (AAV) Wild-Type and Mutant Rep Proteins for Their Abilities To Negatively Regulate AAV p ₅ and p ₁₉ mRNA Levels", <i>Journal</i> of Virology, <u>68</u> :2957-2957 (1994)
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	O	THER ART (Including Author, Title, Date, Pertinent Pages, Etc.)
	вх	Matsushita <i>et al.</i> , "Localization of von Willebrand Factor-binding Sites for Platelet Glycoprotein Ib and Botrocetin by Charged-to-Alanine Scanning Mutagenesis", <i>Journal of Biology Chemistry</i> , <u>275</u> :11044-11049 (2000)
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	BZ	Mendelson <i>et al.</i> , "Identification of the <i>trans</i> -Acting Rep Proteins of Adeno-Associated Virus by Antibodies to a Synthetic Oligopeptide", <i>Journal of Virology</i> , <u>60</u> :823-832 (1986)
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	СВ	Needleman et al., "A General Method Applicable to the Search for Similarities in the Amino Acid Sequence of Two Proteins", Journal of Molec. Biol., 48:443 (1970)
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	CD	Ni et al., "In Vitro Replication of Adeno-Associated Virus DNA", Journal of Virology, 68:1128-1138 (1994)
	CE	Owens et al., "Identification of a DNA-Binding Domain in the Amino Terminus of Adeno-Associated Virus Rep Proteins," J. Virology, 67(2):997-1005 (1993)
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0	THEN ANT (including Author, Title, Date, Fertillent Fages, Etc.)
СК	Press Release 7; "Nautilus Biotech optimizes the AAV rep protein to increase rAAV productivity"; Paris- September 21, 2001; http://www.nautilusbiotech.com/news-pressrelease7.php3, accessed on (2/28/02)
CL	Press Release 6; "Nautilus Biotech S.A. Files a Key Patent Application in the U.S."; Paris-September 14, 2001; http://www.nautilusbiotech.com/news-pressrelease6.php3, accessed on (2/28/02)
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со	Ryan et al., "Sequence Requirements for Binding of Rep68 to the Adeno-Associated Virus Terminal Repeats", Journal of Virology, 70:1542-1553 (1996)
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cv	Tessier <i>et al.</i> , "Characterization of Adenovirus-Induced Inverted Terminal Repeat-Independent Amplification of Integrated Adeno-Associated Virus <i>rep-cap</i> Sequences", <i>Journal of Virology</i> , <u>75</u> :375-383 (2001)
cw	Translation of PCT Patent Application WO 01/44809, "Methods for Screening or Assessing the Performance of a Collection of Biological Agents in Living Parget Cells, And Their Applications"

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FORM PTO-1449 (Modified)	ATTY. DOCKET NO. SERIAL NO. 10/022,249		
LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE	APPLICANT VEGA et al.		
STATEMENT	FILING DATE December 17, 2001	GROUP 1643	

	THEIR ART (including Author, Title, Date, Fertillett Fages, Ltc.)
сх	Urabe <i>et al.</i> , "Charged-to-Alanine Scanning Mutagenesis of the N-Terminal Half of Adeno-Associated Virus Type 2 Rep78 Protein", <i>Journal of Virology</i> , <u>23</u> :2682-2693 (1999)
CY	Walker <i>et al.</i> , "Mutational Analysis of the Adeno-Associated Virus Type 2 Rep68 Protein Helicase Motifs", <i>Journal of Virology</i> , <u>71</u> :6996-7004 (1997)
CZ	Walker <i>et al.</i> , "Mutational Analysis of the Adeno-Associated Virus Rep68 Protein: Identification of Critical Residues Necessary for Site-Specific Endonuclease Activity", <i>Journal of Virology</i> , 71:2722-2730 (1997)
DA	Watson <i>et al.</i> , " <i>Molecular Biology of the Gene</i> ", 4th Ed., The Benjamin/Cummings Pub. Co., p. 224, (1987)
DB	Weitzman <i>et al.</i> , "Interaction of Wild-Type and Mutant Adeno-Associated Virus (AAV) Rep Proteins on AAV Hairpin DNA", <i>Journal of Virology</i> , <u>70</u> :2240-2248 (1996)
DC	Weitzman <i>et al.</i> , "Recruitment of Wild-Type and Recombinant Adeno-Associated Virus into Adenovirus Replication Centers", <i>Journal of Virology</i> , 70:1845-1854 (1996)
DD	Wu et al., "Mutational Analysis of the Adeno-Associated Virus Type 2 (AAV2) Capsid Gene and Construction of AAV2 Vectors with Altered Tropism", J. Virol., 74:8635-8647 (2000)
DE	Yang et al., "Mutational Analysis of the Adeno-Associated Virus rep Gene", Journal of Virology, 66:6058-6069 (1992)
DF	Yang <i>et al.</i> , "Analysis of the Terminal Repeat Binding Abilities of Mutant Adeno-Associated Virus Replication Proteins", <i>Journal of Virology</i> , <u>67</u> : 4442-4447 (1993)
DG	Yoon et al., "Amino-Terminal Domain Exchange Redirects Origin-Specific Interactions of Adeno-Associated Virus Rep78 In Vitro", Journal of Virology, 75:3230-3239 (2001)

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